UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,316	04/26/2001	Evi Kostenis	38005-147	5658

26633 7590 10/22/2002

HELLER EHRMAN WHITE & MCAULIFFE LLP
1666 K STREET,NW
SUITE 300
WASHINGTON, DC 20006

EXAMINER	
ULM, JOHN D	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 10/22/2002 12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/842,316	Applicant(s) Kostenis et al.
	Examiner John Ulm	Art Unit 1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 6, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above, claim(s) *15 and 20-31* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-14, 16-19, and 32* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1) Claims 1 to 32 are pending in the instant application.

2) Claims 15 and 20 to 31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 11.

3) Acknowledgment is made of applicant's claim for foreign priority based on two applications which were filed in Europe on 26 April of 2000 and 01 August of 2000. It is noted, however, that applicant has not filed certified copies of these European applications as required by 35 U.S.C. 119(b).

4) The drawings in the instant application do not comply with 37 C.F.R. § 1.821(d), which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. M.P.E.P. 2422.02 expressly states that "when a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings".

5) The drawings in the instant application do not comply with 37 C.F.R. § 1.84(p)(3), which states that:

> Numbers, letters, and reference characters must measure at least .32 cm. (1/8 inch) in height. They should not be placed in the drawing so as to interfere with its comprehension. Therefore, they should not cross or mingle with the lines. They should not be placed upon hatched or shaded surfaces. When necessary, such as indicating a surface or cross section, a reference character may be underlined

and a blank space may be left in the hatching or shading where the character occurs so that it appears distinct.

Correction is required.

6) The information disclosure statements filed on 26 October of 2001 and 06 December of 2001 fail to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. They have been placed in the application file, but the information referred to therein has not been considered.

7) Claim 19 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A properly dependant claim can not conceivably be infringed without infringing any of the claims from which it depends. Claim 19 can clearly be infringed by a polynucleotide which does not infringe claim 1, from which claim 19 depends. See M.P.E.P. 608.01(n)III..

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8) Claim 9 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of an isolated polynucleotide encoding all or a specific portion of the amino acid sequence presented in SEQ ID NO:2 of the instant application, does not

reasonably provide enablement for using any "fragment" of SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. This claim encompasses any fragment of SEQ ID NO:1. The instant specification appears to indicate that a "fragment" of SEQ ID NO:1 consists of any two or more "contiguous" nucleotide bases. Therefore, the majority of compounds encompassed by this claim are dinucleotides, trinucleotides, quatranucleotides, pentanucleotides etc. The instant specification, however, is silent on the specific use of such small polynucleotide molecules. A claim must be commensurate in scope with the disclosure upon which it is based. A disclosure must provide the guidance needed by one skilled in the art not only to make the claimed invention but also to use it. Because the instant specification does not disclose how to use the majority of molecules encompassed by claim 9, the scope of that claim is not supported by the instant specification.

9) Claims 16 and 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 16 is directed to a process of producing a polypeptide comprising the amino acid sequence of SEQ ID NO:2. Claim 18 is directed to a process of producing a human EDG8 polypeptide. Neither of the claimed processes require the presence of a polynucleotide encoding either SEQ ID NO:2 or a human EDG8 polypeptide. Each of these claims ultimately depend from claim 1, which encompasses an isolated polynucleotide comprising a polynucleotide having at

least about 90% sequence identity to a polynucleotide encoding SEQ ID NO:2. The vast majority of polynucleotides encompassed by claim 1 encode no polypeptide at all. The instant specification, however, does not provide the guidance needed to produce the polypeptides recited in these claims without employing a polynucleotide encoding them.

10) Claim 32 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This claim is directed to a pharmaceutical composition comprising a polynucleotide encoding "EGD8". The limitation "pharmaceutical composition" inherently implies a clinical utility. However, the instant specification lacks the guidance needed to produce a "pharmaceutical composition" comprising a polynucleotide and having a clinical utility. The clinical administration of polynucleotides is not an art accepted practice. The instant specification provides neither the guidance needed to administer a polynucleotide of the instant invention for clinical effect or even a single working example of such administration. Further, there is not a single publication of record which describes the effective administration of a polynucleotide encoding all or a portion of any member of the G protein-coupled receptor family to any mammal for clinical effect. A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc, v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that:

"[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

The instant specification is not enabling because one can not following the guidance presented therein and practice the claimed composition without first making a substantial inventive contribution.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11) Claims 17, 18 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11.1) Claim 17 is vague and indefinite because the identity of the "polypeptide" referred to therein is unspecified.

11.2) Claims 18 and 32 are vague and indefinite in so far as they employ the term "EDG8" as a limitation. Because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of "EDG8" an artisan can

not determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12) Claim 19 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. This claim encompasses a nucleic acid as it occurs in nature.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13) Claims 1 to 14 and 16 to 19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by each of the Glucksmann et al. (WO 00/11166 A1, 02 Mar. 2000) and Behan et al. (WO 00/22131, 20 Apr. 2000) patent publications. The amino acid sequence presented in SEQ ID NO:2 of the instant application appears to be identical to the amino acid sequence presented in Figures 1A and 1B of Glucksmann et al. and amino acid residues 104 to 500 in SEQ ID NO:32 of Behan et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JOHN ULM
PRIMARY EXAM
GROUP 1